



NATIONAL ACTION PLAN ON BREAST CANCER  
A Public/Private Partnership

W O R K I N G G R O U P

JANUARY 1998

THE NATIONAL BIOLOGICAL RESOURCE BANKS WORKING GROUP

By studying normal cells and cancer cells, researchers are beginning to unravel the molecular differences that account for the uncontrolled growth and migration of cancer cells throughout the body. Alterations in certain genes, such as proto-oncogenes, tumor suppressor genes, and cell cycle genes, are thought to play a critical role in the transformation of normal cells into cancer cells. By understand-

ing these molecular differences, researchers hope to develop targeted interventions to more effectively treat cancer and, ultimately, to develop ways of preventing it from ever occurring.

Studies to understand the molecular triggers and inhibitors of breast cancer cell proliferation and migration rely on the availability of normal and breast cancer tissue. Normal and/or cancerous tissue is obtained, with written consent, from women undergoing breast surgery. This tissue is then made available for research studies.

Currently, no national system for obtaining, storing, and registering this tissue exists, and some researchers have difficulty obtaining tissue to address specific research questions. Adequate tissue samples to answer questions about molecular differences among cancers of different stages; different rates of growth; or from women of different ages, races, or geographic regions may not be available to them currently but would be accessible from a national system. Additionally, a national system would ensure protection of full informed consent for tissue procurement, the rights and privacy of women who donate breast tissue for research, and the maintenance of an adequate supply of tissues with various characteristics.

The NAPBC's National Biological Resource Banks Working Group was formed to address this priority area. Its charge is to establish a national system of biological resource banks to ensure a resource of well-characterized and well-documented biological materials to explore multiple issues in breast cancer research.

CURRENT ACTIVITIES AND ACCOMPLISHMENTS

The Working Group has focused on three key areas: (1) determining the availability and adequacy of existing sources of biological materials used in breast cancer research; (2) exploring the ethical and legal issues, including informed consent, involved in collecting, using, and storing biological materials; and (3) determining the need for a centralized national biological resource banks network.

WHAT IS THE NAPBC?

The National Action Plan on Breast Cancer (NAPBC) was established in 1993 in response to a National Breast Cancer Coalition petition signed by 2.6 million people and presented to President Clinton. The petition called for a coordinated national strategy to combat breast cancer, the second leading cause of cancer deaths among American women.

The mission of the NAPBC is to stimulate rapid progress in eradicating breast cancer. The strategy for the Plan is to:

- *encourage new ideas and define unaddressed breast cancer priority areas.*
- *serve as a catalyst for national efforts to advance breast cancer knowledge, research, policy, and services.*
- *mobilize partnerships and coordinate actions among diverse public and private sector organizations and individuals.*

The work of the NAPBC is guided by a Steering Committee and Working Groups. The Steering Committee provides oversight for and ensures coordination across NAPBC initiatives. The Working Groups correspond to Plan priorities and identify, recommend, and oversee implementation of Plan activities. Plan implementation is coordinated by the U.S. Public Health Service's Office on Women's Health. Currently, there are six Working Groups. This fact sheet describes the National Biological Resource Banks Working Group.

### Survey of Sources of Biological Tissues

The Working Group, in collaboration with the National Cancer Institute (NCI), conducted a survey of existing public and private sources of biological tissues, cell lines, and other biological material. This survey identified sources of biological materials and assessed the degree to which materials are accessible and available from these sources. The results of this effort have been compiled in a database, the Breast Cancer Specimen and Data Information System (BCSDIS). The Working Group advertised and marketed the BCSDIS, including the development and distribution of a brochure that describes the system and how to access it. The system is available to interested researchers on the Internet at <http://cancernet.nci.nih.gov/breastdata>.

#### WORKING GROUP ACCOMPLISHMENTS

*Conducted a large-scale survey to identify sources of biological tissues, cell lines, and other biological materials that can be used in breast cancer research.*



*Created the Breast Cancer Specimen and Data Information System, which allows for wide availability of biological materials information.*



*Surveyed researchers to learn about their needs for breast cancer tissues.*



*Developed guidelines on the ethical use of biological materials, such as breast tissue, in research.*



*Drafted and refined model informed consent forms for use by researchers when they obtain breast tissue.*



*Convened a major conference to develop procedures for establishing a national biological resource banks network.*

### Survey of Researchers' Needs for Biological Tissues

In a second, complementary activity, the Working Group surveyed researchers to learn about their needs for breast cancer tissues—how much tissue they use and need, what kinds of tissue are required, and for what purposes. The survey also gathered information on the types of researchers who use breast cancer tissue and the types of research they conduct. The Working Group was particularly interested in collecting information from scientists who are just starting their careers to determine whether increased access to biological materials would encourage these scientists to conduct molecular research. After results from this survey were analyzed, the final report on this activity was disseminated to a variety of researchers and placed on the NAPBC Web site (<http://www.napbc.org>).

### Conference on Establishment of National Biological Resource Banks

Following up on the findings from these activities, the Working Group held a conference in September 1996 to discuss the practical issues associated with developing and establishing national biological resource banks. Participants reached consensus and developed recommendations about how tissue available for breast cancer research can be collected, sorted, and deposited in tissue banks for use by researchers. Issues such as cost, consent, and recordkeeping also were addressed. The recommendations can be viewed on the NAPBC Web site. NCI has hired an ombudsman to

serve as a central point of contact for researchers needing biological materials for breast and other cancer research studies. Information on tissue repositories can be obtained on the NCI Web site at <http://www-cbctr.ims.nci.nih.gov> or by contacting Marianna Bledsoe of the Cancer Diagnosis Program, National Cancer Institute, National Institutes of Health at (301) 496-7147.

### **Guidelines on the Ethical Use of Biological Tissues**

Ensuring an adequate supply of tissue for breast cancer research is a critically important task. But even more important is ensuring the rights of the individuals whose tissue is used. The Working Group has addressed this priority by developing guidelines on the ethical use of biological tissues. These guidelines provide a framework within which consumers can donate and scientists, pathologists, and researchers can obtain, use, and store tissues for breast cancer research. The Working Group conducted an extensive review of relevant writings dealing with medical, legal, and ethical issues and consulted with existing groups whose members have a stake in processing, storing, and using tissue. A February 1996 workshop was convened to develop draft guidelines on ethical and legal issues related to the use of biological tissues. After receiving comments from a wide array of scientists, surgeons, pathologists, ethicists, lawyers, consumer advocates, and professional societies, the Working Group convened a second workshop in June 1997 to develop final guidelines for Institutional Review Boards (IRBs) and others. These guidelines were presented at the Public Responsibility in Medicine and Research (PRIM&R) annual meeting in December 1997. PRIM&R will further modify and disseminate the guidelines to researchers, ethicists, professional societies, IRBs, and advocates. The June 1997 workshop summary can be viewed on the NAPBC Web site.

#### **FOR MORE INFORMATION**

For more information about the National Biological Resource Banks Working Group and its activities, please contact:

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In conjunction with this activity, the Working Group has developed and focus group tested an easy-to-read model patient consent form that can be used by researchers as they obtain biological tissues. A report of the focus groups was presented to the President's National Bioethics Advisory Committee and other professional and consumer groups addressing informed consent and patients' rights issues. The Working Group also has developed a patient fact sheet on the use of tissue for research that can be used with the consent form. NCI plans to coordinate and support field tests to validate the model consent form. Both the model patient consent form and the patient fact sheet are available on the NAPBC Web site.

#### **FUTURE PLANS**

This Working Group will convene in the spring of 1998 to assess its accomplishments in the context of meeting its overall goals and objectives.